

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: KUZ-0024  
Inventors: Ito et al.  
Serial No.: Not Yet Assigned  
Filing Date: Herewith  
Examiner: Not Yet Assigned  
Group Art Unit: Not Yet Assigned  
Title: Transdermal Patch for External Use  
Comprising Fentanyl

"Express Mail" Label No. EV626224545US  
Date of Deposit April 15, 2005

I hereby certify that this paper is being deposited with the  
United States Postal Service "Express Mail Post Office  
to Addressee" service under 37 CFR 1.10 on the date  
indicated above and is addressed to the Commissioner for Patents  
Post Office Box 1450, Box PCT, Alexandria, VA 22313-1450

By Kathleen A. Tyrrell  
Typed Name: Kathleen A. Tyrrell, Reg. No. 38,350

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

- (XX) In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.
- ( ) In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:
- ( ) Certification in Accordance with §1.97(e) is attached hereto; or
- ( ) Authorization to charge Deposit Account No. 50-1619 the fee of \$180.00 as set forth in §1.17(p) is provided.
- ( ) In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in §1.17(I) (1).

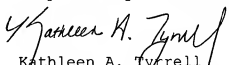
(XX) Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith.

( ) In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. \_\_\_\_\_, filed \_\_\_\_\_, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-1619. This form is submitted in duplicate.

(XX) References AA, BA, BB, BC, BD and BJ are in the English language. References BA, BB, BC, BD and BJ relate to references BE, BI, BG, BH and BK, respectively. English Abstracts are provided for References BF and BL.

Respectfully submitted,

  
Kathleen A. Tyrrell  
Registration No. 38,350

Date: April 15, 2005

Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053

(856) 810-1515

Sheet 02 of 03

<b>Form PTO-1449 Modified</b> List of Patents and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce	Docket No. <b>KUZ-0024</b>	Serial No. <b>104531433</b> Not Yet Assigned
	Applicant <b>Ito et al.</b>	
	Filing Date Herewith	Group Not Yet Assigned

**U. S. PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Name	Class	Subclass
/M.Y./	BA	6,139,866	10-31-00	Chono et al.	424	443
/M.Y./	BB	4,588,580	5-13-86	Gale et al.	424	21
/M.Y./	BC	2003/0109819	6-12-03	Tsuruda et al.	602	48
/M.Y./	BD	5,770,221	6-23-98	Nakamura et al.	424	449

**FOREIGN PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Country	Translation YES	NO
/M.Y./	BE	10-45570	2-10-98	Japan	Relates to BA	
/M.Y./	BF	04-095023	3-27-92	Japan	English Abstract	
/M.Y./	BG	WO 01/43729 A1	6-21-01	Japan	English Abstract and Ref. BC	
/M.Y./	BH	WO 95/31190	11-23-95	Japan	English Abstract and Ref. BD	
/M.Y./	BI	61-37725	2-22-86	Japan	English Abstract and Ref. BB	

EXAMINER /Micah Paul Young/ (03/31/2008)	DATE CONSIDERED 03/31/2008
---------------------------------------------	-------------------------------

Sheet 03 of 03

<b>Form PTO-1449 Modified</b> List of Patents and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce	Docket No. <b>KUZ-0024</b>	Serial No. <b>104531433</b> Not Yet Assigned
	Applicant <b>Ito et al.</b>	
	Filing Date <b>Herewith</b>	Group Not Yet Assigned

## U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass

## FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation YES	NO
/M.Y./	BJ	WO 91/16085	10-31-91	PCT	x	
/M.Y./	BK	5-507682	11-5-93	Japan	Relates to Ref. BJ	
/M.Y./	BL	2000-044476	2-15-00	Japan	English Abstract	

EXAMINER	/Micah Paul Young/ (03/31/2008)	DATE CONSIDERED	03/31/2008
----------	---------------------------------	-----------------	------------

Sheet 01 of 03

<b>Form PTO-1449 Modified</b>  List of Patents and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce		Docket No. <b>KUZ-0024</b>	Serial No. <b>10/531433</b> Not Yet Assigned
		Applicant <b>Ito et al.</b>	
		Filing Date <b>Herewith</b>	Group <b>Not Yet Assigned</b>
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
/M.Y./	AA	Roy et al., "Controlled Transdermal Delivery of Fentanyl: Characterizations of Pressure-Sensitive Adhesives for Matrix Patch Design", Journal of Pharmaceutical Sciences 1996 85(5):491-495	
<b>EXAMINER</b>		/Micah Paul Young/ (03/31/2008)	
		<b>DATE CONSIDERED</b>	03/31/2008